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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,707	10/27/2005	Masataka Kuwana	4439-4036	2198

27123 7590 08/10/2007  
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NEW YORK, NY 10281-2101

EXAMINER
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DUTT, ADITI

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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08/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,707	<b>Applicant(s)</b> KUWANA ET AL.	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/8/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-16 and 19-22 is/are pending in the application.  
     4a) Of the above claim(s) 9-16, 19, 20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-8, 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 2-16 and 19-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413).<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/30/07</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Appendix A-see 892</u> .                |

## **DETAILED ACTION**

### ***Status of Claims***

1. The amendment filed on 8 May 2007 has been entered into the record and has been fully considered. Claims 2-8, 21, are amended. Claims 1, 17-18 are canceled.
2. Claims 2-8 and 21, are pending in the instant application. Claims 2-8 and 21, directed to a monocyte derived multipotent cell, are under examination in the instant office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
4. Applicant's arguments filed on 8 May 2007, have been fully considered. New grounds of objection and rejection are as follows.

### ***Response to Amendment***

#### **Withdrawn objections and/or rejections**

5. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (8 May 2007).
6. Applicant's submission of replacement drawings and amended specification to coincide with the new numbering of the drawings has been acknowledged and considered.

7. Upon consideration of the amendment to claims 2-8, and 21, rejection of claims 2-8, and 21, under 35 USC § 112-second paragraph is withdrawn. It is, however, suggested that the term "nerve" in claim 6 be rephrased to indicate specific nerve cells (e.g. neuron) for clarification.
8. Upon consideration of the amendment to claims 2-8, rejection of claims 2-8, under 35 USC § 101-non-statutory subject matter is withdrawn.
9. Upon consideration of the cancellation of claims 17-18, rejection of claims 17-18, under 35 USC § 112-first paragraph, lack of enablement is withdrawn.

Claim rejections/objections maintained/new grounds of rejection

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2-8, stand rejected under 35 U.S.C. 102(b) as anticipated by Zhao et al., (PNAS 100: 2426-2431, 2003), for reasons of record in the Office Action, dated 8 February 2007.

11. Applicant argues that the Zhao reference does not teach collagen type I as “stipulated in the claimed invention” and “therefore, merely for this reason the claimed invention is not anticipated by Zhao et al”. Applicant further disagrees with the Examiner’s Action, because MOMC cannot differentiate to epithelial and hepatocyte cells, which belong to the hematopoietic family and not the claimed mesenchymal or mesodermal family. Hence MOMC and the pluripotent stem cells (PSC) of Zhao et al. accomplish different cell differentiation, thus are different. Therefore, the rejection is requested to be withdrawn.
12. Applicant’s arguments have been fully considered but have not been found to be persuasive. As stated in the previous Office Action, Zhao et al. teach differentiation of PSC from human peripheral blood monocytes that resemble fibroblasts and express differentiation stem cell markers, such as CD14, CD34 and CD45. Although the reference is silent on the expression of collagen type I, this would be an inherent characteristic, because the cells are derived from monocytes isolated from the peripheral blood mononuclear cells. Furthermore, the monocytes of the reference resemble fibroblasts, which as evidenced by He et al. (Stem Cells 25: 69-77, 2007; page 73, col 1, para 1) are present as “fibrocyte” mediating tissue repair during injury, and which inherently possess the phenotype of collagen type I. He et al. further indicate that MOMC, or previously called MOMP (monocyte derived mesenchymal progenitors) cells, also exhibit similar morphology to fibrocytes and share similar surface markers as the fibrocytes (page 73, col 1, para 2). Thus, according to He et al., MOMC are

morphologically and phenotypically identical to the PSC of Zhao et al. Since MOMC and PSC are derived from the same source, and possess similar characteristics as explained above, the two inherently display the same differentiation and express similar marker, absent evidence to the contrary. That the reference is silent on the expression of one marker does not provide proof of the cell being different, particularly if the other conditions (as stated above) are satisfied.

13. Furthermore, as stated in the previous Office Action, it is reiterated that the monocytes, macrophages, lymphocytes etc., are blood cells of hematopoietic origin, that "are able to" differentiate to mesenchymal or mesodermal cells (see Figure 1.1, Appendix A). Moreover, an overlap of morphology and phenotypes within the hematopoietic and mesenchymal cells, is discerned in the relevant art, that adds to the confusion in the classification of the various cell populations (He et al., page 73, col 2, para 1; page 74, col 1 and 2). In view of the above evidence, the reference clearly anticipates the claimed invention.

14. Accordingly, and in contrast to Applicant's arguments on pages 15 and 16 of the response, it has been established by the courts that a product (i.e. as it relates to the claimed monocyte derived multipotent cell) inherently possesses characteristics of that product (i.e., any expressed marker or non-expressed marker, such as being type I collagen positive), and that:

"the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.

Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, Appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al., (PNAS 100: 2426-2431, 2003, as applied to claims 2-8 above), in view of Pujol et al. (Differentiation 65: 287-300, 2000), for reasons of record in the Office Action, dated 8 February 2007.
16. Applicant alleges that since the amended claim 21 depends from the amended claim 2 that recites the expression of CD14, CD 34, CD45 and type I collagen, and since Applicant believes that Zhao et al do not teach collagen type I marker, the cited art does not "make the dependent claim 21 obvious" over Zhao et al.
17. Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous Office Action (page 10, para 29) and further explained in details above,  
  
"It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the in vitro culture of PBMCs of Zhao et al. to

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conduct the culture on fibronectin coated plates as taught by Pujol et al. The person of ordinary skill in the art would have been motivated to make that modification and would have expected success because of its well-established use in tissue-culture methods to promote attachment, spreading and proliferation of various cell types”.

Therefore, the claimed invention is *prima facie* obvious over the combined teachings of Zhao et al and Pujol et al. and the rejection is maintained.

18. Furthermore, it is noted that the courts have held that when the prior art product reasonably appears to the same as that claimed, but differs in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972))

### ***Conclusion***

19. No claims are allowed.
20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
21. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory




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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER

AD   
18 July 2007